Serial No.: 09/900,707 - 3 - Art Unit: 3732

Confirmation No.: 4890

### **REMARKS**

Claims 46-64 are pending for examination with claims 46, 53 and 59 being independent claims.

### Allowable Subject Matter

Applicants acknowledge the Examiner's indication that claims 48 and 49 would be allowable if rewritten in independent form including all of the limitations of their respective base claim and any intervening claims. These claims have not been rewritten in independent form because these depend from claims believed to be allowable as discussed below.

### Rejections Under 35 U.S.C. § 102

Claims 46, 50, 53, 54, 56, 59, 60, and 62 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mulhauser (U.S. patent No. 5,766,246). The Examiner contends that Mulhaser discloses a prosthesis and method of implanting a prosthesis that includes a polypropylene mesh layer, a barrier layer as shown in Fig. 3h, and an edge barrier as shown in Fig. 3h. Applicants respectfully traverse these rejections.

### Claims 46 and 50

Independent claim 46 is directed to a prosthetic repair fabric for repairing a tissue or muscle wall defect. the prosthetic repair fabric comprises a layer of mesh fabric with a plurality of interstices that are constructed and arranged to allow tissue ingrowth. The mesh fabric is susceptible to the formation of adhesions with sensitive tissue and organs, and includes first and second sides and an edge extending between the first and second sides. The prosthetic repair fabric also comprises at least one barrier layer that inhibits the formation of adhesions with sensitive tissue and organs. The barrier layer is disposed on at least a portion of one of the first and second sides of the layer of mesh fabric to inhibit the formation of adhesions between the portion of the mesh fabric and adjacent sensitive tissue and organs. The prosthetic repair fabric further comprises an edge barrier that inhibits the formation of adhesions with sensitive tissue and organs. The edge barrier is adapted to isolate at least a portion of the edge of the mesh fabric from adjacent sensitive tissue and organs.



Serial No.: 09/900,707 - 4 - Art Unit: 3732

Confirmation No.: 4890

Mulhauser is directed to an implantable prosthesis 10 having a mesh layer 12 and a semirigid frame 14 supporting a body of the mesh layer. (Mulhauser, Col. 3, lines 39-49). As shown in Figs. 2 and 3h, the frame may be configured to extend over the mesh layer at both the peripheral edge of the mesh layer and the surface margin of the mesh layer adjacent the peripheral edge.

Applicants respectfully submit that Mulhauser fails to anticipate claim 46. More particularly, Mulhauser does not teach or suggest a prosthetic repair fabric including an edge barrier that inhibits the formation of adhesions with sensitive tissue and organs as recited in claim 46. The Examiner appears to contend that the Mulhauser frame 14 is both an edge barrier and a surface barrier. Applicants respectfully disagree.

Mulhauser does not teach or suggest that the frame 14 has any type of adhesion inhibiting properties. Mulhauser only indicates that the frame 14 may be formed from a polypropylene material or a silicone material, or that the frame may be formed by hot or cold forming a ring-shaped depression in the mesh layer itself. (Mulhauser, Col. 4, lines 60-65). These materials for the frame 14 are not inherently resistant to adhesions. Rather, various factors such as surface texture and pore size of the material of the frame affect its ability to inhibit adhesions. One of ordinary skill in the art would not recognize the frame as necessarily inhibiting the formation of adhesions. Thus, Mulhauser does not disclose an edge barrier which inhibits the formation of adhesions with sensitive tissue and organs as recited in claim 46.

In view of the foregoing, claim 46 patentably distinguishes over Mulhauser, such that the rejection under § 102 should be withdrawn. Claim 50 depends from claim 46 and is patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

### Claims 53-56

Independent claim 53 is directed to an implantable prosthesis for repairing a tissue or muscle wall defect. The implantable prosthesis comprises a layer of repair fabric that is susceptible to the formation of adhesions with tissue and organs. The layer of repair fabric includes first and second sides and an edge extending between the first and second sides. The implantable prosthesis also comprises a barrier layer that inhibits the formation of adhesions with tissue and organs and is configured to inhibit the formation of adhesions between at least a portion of one of the first and second sides and adjacent tissue and organs. The implantable



Serial No.: 09/900,707 - 5 - Art Unit: 3732

Confirmation No.: 4890

prosthesis further comprises an edge barrier which inhibits the formation of adhesions with tissue and organs and is adapted to cover at least a portion of the edge of the layer of repair fabric to inhibit the formation of adhesions between the portion of the edge of the layer of repair fabric and adjacent tissue and organs.

Applicants respectfully submit that Mulhauser does not anticipate claim 53. As discussed above, the Mulhauser prosthesis includes a mesh fabric with a peripheral frame. Mulhauser does not disclose any adhesion inhibiting characteristics of the frame. Thus, Mulhauser does not teach or suggest an edge barrier which inhibits the formation of adhesions with tissue and organs as recited in claim 53.

In view of the foregoing, claim 53 patentably distinguishes over Mulhauser, such that the rejection under § 102 should be withdrawn. Claims 54-56 depend from claim 53 and are patentable for at least the same reasons. Accordingly, withdrawal of these rejections is respectfully requested.

### Claims 59, 60 and 62

Independent claim 59 is directed to a method of repairing a tissue or muscle wall defect and comprises the step of providing an implantable prosthesis. The prosthesis includes a layer of repair fabric which is susceptible to the formation of adhesions with tissue and organs. The layer of repair fabric includes first and second sides and an edge extending between the first and second sides. The prosthesis also includes a barrier layer that inhibits the formation of adhesions with tissue and organs. The barrier layer is configured to inhibit the formation of adhesions between at least a portion of the first side and adjacent tissue and organs. The implantable prosthesis further includes an edge barrier which inhibits the formation of adhesions with tissue and organs. The edge barrier covers at least a portion of the edge of the layer of repair fabric to inhibit the formation of adhesions between the portion of the edge of the layer of repair fabric and adjacent tissue and organs. The method further comprises the step of implanting the implantable prosthesis with the barrier layer and the edge barrier being positioned between the layer of repair fabric and a region of potential adhesions with tissue and organs.

Applicants respectfully submit that Mulhauser does not anticipate claim 59. As discussed above, the Mulhauser prosthesis includes a mesh fabric with a peripheral frame. Mulhauser does not disclose any adhesion inhibiting characteristics of the frame. Thus, Mulhauser does not teach

Serial No.: 09/900,707 - 6 - Art Unit: 3732

Confirmation No.: 4890

or suggest an edge barrier which inhibits the formation of adhesions with tissue and organs as recited in claim 59.

In view of the foregoing, claim 59 patentably distinguishes over Mulhauser, such that the rejection under § 102 should be withdrawn. Claims 60 and 62 depend from claim 59 and are patentable for at least the same reasons. Accordingly, withdrawal of these rejections is respectfully requested.

## Rejections Under 35 U.S.C. § 103

The Office Action rejected claims 47, 51, 52, 55, 57, 58, 61, 63, and 64 under 35 U.S.C. § 103(a) as being unpatentable over Mulhauser in view of Eldridge (U.S. 6,120,539). Applicants respectfully traverse these rejections.

Without acceding to the propriety of the combination as suggested by the Examiner, claims 47, 51, and 52 depend from claim 46 and are patentable for at least the same reasons set forth above. Similarly, claims 55, 57, 58, 61, 63, and 64 depend from claim 53 and are patentable for at least the same reasons set forth above. Accordingly, withdrawal of these rejections is respectfully requested.

Serial No.: 09/900,707 - 7 - Art Unit: 3732

Confirmation No.: 4890

# **CONCLUSION**

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicants' attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By:

Carole A. Boelitz, Reg. No. 48,958

James M. Hanifin, Jr., Reg. No. 39,213

Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2211

Telephone: (617) 720-3500

Docket No. D00188.70126.US

Date: July <u>/o</u>, 2003

x07/11/03

